III. **510(k) SUMMARY**
(As required by 21 C.F.R. 807.92)

A. Submitter Information

Submitter's Name:	Thomas Medical Products, Inc.
Address:	65 Great Valley Parkway Malvern, PA 19355
Telephone Number:	(610) 296-3000
Facsimile:	(610) 296-4591
Contact Person:	Peter J. Rapp
Title:	Director, Quality Assurance/Regulatory Affairs
Date Submission Prepared:	December 21, 2000

B. Device Information

Trade name:	n/a
Classification Names:	Catheter Introducer (21 C.F.R. §870.1340), Vessel Dilator for Percutaneous Catheterization (21 C.F.R. §870.1310), Percutaneous Catheter (21 C.F.R. §870.1250)
Predicate Devices:	Boston Scientific Corporation , Intracardiac Introducing Sheath and Accessories, (K992309).
Device Description:	The Thomas Medical Braided Guiding Introducers are designed to provide a conduit to deliver diagnostic and therapeutic catheters to specific heart chambers and locations in the heart. The sheath may be used for percutaneous entry. Each Braided Guiding Introducer consists of the following: (1) a sheath, (2) a dilator, and (3) a J-tipped guide wire. In addition, a standard 12cc syringe, A 18 gauge XTW introducer needle and a pre-dilator may also be packaged with the Braided Guiding Introducer kit.
Intended Use:	The Braided Guiding Introducer is for the percutaneous introduction of various types of cardiovascular catheters to all heart chambers, including the left atrium via transseptal puncture.

C. Comparison of Required Technological Characteristics

The technological characteristics of the Modified Device are the same as the Predicate Device.

D. Substantial Equivalence

The Thomas Medical Products Braided Guiding Introducer has the same general intended use/indications for use and technological characteristics as other previously cleared devices. Therefore, based on the similarities in intended use and technological characteristics, the Thomas Medical Products Braided Guiding Introducer is substantially equivalent to the legally marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL - 9 2001

Mr. Peter J. Rapp
Director, Quality Assurance/Regulatory Affairs
Thomas Medical Products, Inc.
65 Great Valley Parkway
Malvern, PA 19355

Re: K004026
Braided Guiding Intrducer
Regulation Number: 870.1340
Regulatory Class: II
Product Code: DYB
Dated: April 19, 2001
Received: April 20, 2001

Dear Mr. Rapp:

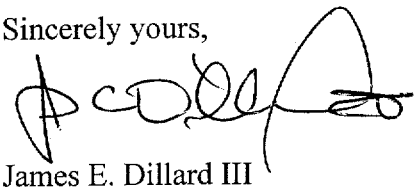
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4586. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,



James E. Dillard III
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): _____

Device Name: Braided Guiding Introducer

Indications For Use:

For the percutaneous introduction of various types of cardiovascular catheters to all heart chambers, including the left atrium via transseptal puncture.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Cardiovascular & Respiratory Devices
510(k) Number K004026

Prescription Use X OR Over-The-Counter-Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)